

Remarks

Claims 2 and 7 to 18 were pending and before the Examiner. By this Amendment, claims 12, 13, and 16 have been amended. As no new matter has been added thereby, entry of the amendments is respectfully requested. Claims 2 and 7 to 18, as amended, are now pending and before the Examiner.

The Examiner objected to the specification.

In response, applicants have amended claims 12, 13, and 16 to render the Examiner's rejection moot and respectfully request that the objection be reconsidered and withdrawn.

The Examiner rejected claims 2, 7, and 14 to 17 as allegedly anticipated under 35 U.S.C. § 102(b) over De Gasparo *et al.* (WO 01/76573), in light of Robl *et al.* (U.S. Patent Appl. Pub. No. 2002/0013334) cited to show a fact.

In response, applicants traverse the Examiner's rejection. De Gasparo *et al.* does not specifically disclose the specific combination of telmisartan and atorvastatin anywhere and the Examiner has not pointed out how De Gasparo *et al.* thereby anticipates the claimed invention. The teachings and statements in De Gasparo *et al.* must be considered in context and interpreted as a whole. De Gasparo *et al.*, at page 1, lines 27 to 29, cited by the Examiner does not represent the complete teaching of De Gasparo *et al.*, because the complete teaching at least also includes page 1, line 30, i.e., "(iii) an ACE inhibitor or a pharmaceutically acceptable salt thereof". De Gasparo *et al.* does not seem to give any preference to any particular combination within the broad disclosure, certainly not a specific combination of telmisartan and atorvastatin. Indeed, De Gasparo *et al.*, at page 3, line 22, merely defines "AT₁ receptor antagonists" as including a number of commercially available sartans including telmisartan, but, contrary to the assertion of the examiner, telmisartan in De Gasparo *et al.* is not disclosed as a selected compound in the context of a specific combination, much less with atorvastatin. The only sartan which is specifically mentioned in De Gasparo *et al.* in the context of a specific combination is valsartan. Similarly, in De Gasparo *et al.*, atorvastatin is mentioned on page 5, lines 6 and 10, but is not mentioned in the context of a specific combination, much less with telmisartan. On page 5, line 26, De Gasparo *et al.* teaches that atorvastatin is a preferred composition partner with valsartan (not telmisartan). De Gasparo

et al. on page 6, line 8 refer to the combination of statins such as atorvastatin with ACE inhibitors (there is no analogous teaching with regard to AT₁ receptor antagonists). Since De Gasparo *et al.* does not specifically disclose the specific combination of telmisartan and atorvastatin, it does not anticipate the instant claims. Accordingly, the anticipation rejection should be reconsidered and withdrawn.

The Examiner also rejected claims 2 and 7 to 18 as allegedly unpatentable under 35 U.S.C. § 103(a) over De Gasparo *et al.*, in light of Robl *et al.*, in view of Cecil's Textbook of Medicine (2000), Harlan *et al.* (U.S. Patent Appl. Pub. No. 2001/0006656), and Bohm *et al.* (WO 02/15891).

Applicants respectfully traverse the rejection. A *prima facie* case of obviousness generally requires the satisfaction of three criteria: (i) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings; (ii) there must be a reasonable expectation of success; and (iii) the references when combined must teach or suggest all of the claim limitations. See M.P.E.P. § 2143. As explained above, De Gasparo *et al.* does not disclose or suggest the specific combination of telmisartan and atorvastatin anywhere, nor does Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, or Bohm *et al.* provide what De Gasparo *et al.* lacks in providing a motivation, reasonable expectation of success, or teaching or suggestion of all of the claim limitations of the claimed invention.

Furthermore, neither De Gasparo *et al.*, Robl *et al.*, Cecil's Textbook of Medicine, Harlan *et al.*, nor Bohm *et al.* teach or suggest that telmisartan increases the expression of genes regulated by the PPARgamma receptor, i.e., an activity known from antidiabetic drugs, which is the reason that telmisartan is a preferred combination partner for atorvastatin in the treatment of, e.g., diabetes, and this metabolic activity appears to be unique for telmisartan and not recognized in the prior art. Indeed, De Gasparo *et al.* teaches the use of AT₁ receptor antagonists of "differing structural features" and therefore suggests that the specific chemical structure is of no concern and none of the other art cited makes up for this defect. Furthermore, neither Harlan *et al.* (disclosing an aerosol formulation of statins) nor Bohm *et al.* (disclosing a combination of telmisartan with ACE inhibitors) disclose, suggest, or hint at telmisartan combinations with statins and it is unclear why or how one of skill in the art at the

time the claimed invention was made would combine their teachings with De Gasparo *et al.* Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

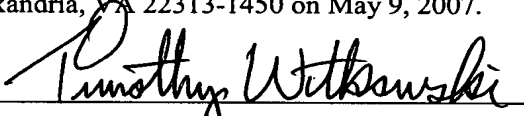
The Examiner also provisionally rejected claims 2 and 7 to 15 for nonstatutory obviousness-type double patenting over claims 1 and 8 to 35 of U.S.S.N. 10/757,015, in view of Harlan *et al.*; provisionally rejected claims 2, 7 to 11, and 14 to 18 for nonstatutory obviousness-type double patenting over claims 1 to 10, 12 to 15, and 18 to 25 of U.S.S.N. 10/899,784; and provisionally rejected claims 2, 7, and 12 to 18 for nonstatutory obviousness-type double patenting over claims 1 to 21 of U.S.S.N. 11/300,947 in view of Drug Facts and Comparisons (1996).

In response, applicants undertake to file a terminal disclaimer with respect to U.S.S.N. 10/757,295, U.S.S.N. 10/899,784, or U.S.S.N. 11/300,947, if (1) the instant claims be found otherwise allowable, and (2) applicants determine that such application poses a double patenting issue at that time. Accordingly, applicants respectfully request that the Examiner withdraw these provisional rejections for consideration later.

Applicants submit that all the pending claims are allowable and respectfully solicit a Notice of Allowance for all of the pending claims. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the attorney below.

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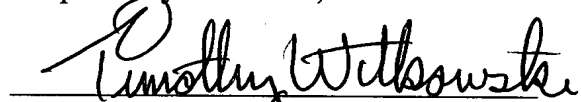


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Dated

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